IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WILLIAM T. JACOBS, JR.,	)	
	)	
	)	Case No. 09 C 1544
Plaintiff,	)	
	)	Judge Virginia M. Kendall
v.	)	
	)	
THE GUARDIAN LIFE INSURANCE COMPANY OF AMERICA and BILL JACOBS MOTORSPORT, INC. HEALTH INSURANCE PLAN,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff William T. Jacobs, Jr. ("Jacobs") filed suit against Defendants Guardian Life Insurance Company of America ("Guardian") and Bill Jacobs Motorsport, Inc. Health Insurance Plan ("the Plan") (collectively "Defendants") pursuant to Sections 502(a)(1)(B) and 502(a)(3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1145, seeking recovery of health insurance benefits. Jacobs and Defendants have filed cross-motions for summary judgment. For the reasons stated below, the Court denies Jacobs' Motion for Summary Judgment and grants Defendants' Cross-Motion for Summary Judgment.

STATEMENT OF UNDISPUTED FACTS[1]

[1] Throughout this Opinion, the Court refers to the Parties' Local Rule 56.1 Statements of Undisputed Material Facts as follows: citations to Jacobs' Statement of Uncontested Facts have been abbreviated to "Pl. 56.1 Exhibit __, p. __."; citations to Defendants' Statement of Uncontested Facts have been abbreviated to "Def. 56.1 Exhibit __, p.__."; citations

Jacobs is employed by Bill Jacobs Motorsport, Inc., a car dealership in Naperville, Illinois. (Def. 56.1 Resp. ¶ 2.) Guardian issued a health insurance policy ("the Policy") to Jacobs Motorsport providing benefits to its employees; as such, Guardian qualifies as a fiduciary under 29 U.S.C. § 1002(21)(A). (Def. 56.1 Resp. ¶¶ 2, 4, 6; Pl. 56.1 Resp. ¶ 3.) At all times relevant to this litigation, the Plan offered health insurance benefits to Jacobs through the Policy issued by Guardian. (Pl. 56.1 Resp. ¶ 4.) As such, Jacobs qualifies as a participant under 29 U.S.C. § 1002(1). (Pl. 56.1 Resp. ¶ 4.) Guardian insured the Policy, processed claims under the Policy, and made determinations of benefits eligibility under the Policy. (Def. 56.1 Resp. ¶ 3; Pl. 56.1 Resp. ¶ 6.)

In 2004, Jacobs was diagnosed with a rare form of bile duct cancer called metastatic cholangiocarcinoma. (Def. 56.1 Resp. ¶ 11.) Jacobs has been under the care of Dr. Thomas Brown, Chief Operating Officer and Professor of Medicine at the University of Arizona College of Medicine Cancer Center and other physicians at the University of Texas MD Anderson Cancer Center ("MD Anderson") since that time. (Def. 56.1 Resp. ¶ 12.)

I. Jacobs' Medical History and Benefit Claims

A. Intensity Modulated Radiation Therapy

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to Defendants' Response to Jacobs' Statement of Uncontested Facts have been abbreviated to "Def. 56.1 Resp. ¶ __." ; citations to Jacobs' Response to Defendants' Statement of Material Facts and Statement of Additional Material Facts have been abbreviated to "Pl. 56.1 Resp. ¶ __."; and citations to Defendants' Response to Jacobs' Statement of Additional Material Facts have been abbreviated "Def. 56.1 Resp. Add. Facts ¶ __."

The Court notes that both parties have failed to comply with Local Rule 56.1. Neither party has supplied the Court with "short" statements of fact and Defendants' statements of fact are frequently without support in the cited record. *See* L.R. 56.1 (the statement of material facts "shall consist of short numbered paragraphs, including within each paragraph specific references to the affidavits, parts of the record, and other supporting materials relied upon to support the facts set forth in that paragraph"). Nonconformity with the Local Rules and the standing orders of the Court is not without consequence. The Seventh Circuit has "repeatedly held that a district court is entitled to expect strict compliance with Rule 56.1." *Ammons v. Aramark Uniform Servs., Inc.*, 368 F.3d 809, 817 (7th Cir. 2004) (citing *Bordelon v. Chicago School Reform Bd. of Trustees*, 233 F.3d 524, 527 (7th Cir. 2000)). "A district court does not abuse its discretion, when, in imposing a penalty for a litigant's non-compliance with Local Rule 56.1, the court chooses to ignore and not consider the additional facts that a litigant has proposed." *Cichon v. Exelon Generation Co., L.L.C.*, 401 F.3d 803, 809-10 (7th Cir. 2005). Accordingly, this Court will not consider portions of the parties' submissions that are non-responsive or do not contain proper support from citations to the record.

After Jacobs' initial chemotherapy treatments ended in November 2005, his treating physician began a regimen of Intensity Modulated Radiation Therapy ("IMRT") to the liver with concurrent chemotherapy and radiation therapy. (Pl. 56.1 Resp. ¶ 8; Def. 56.1 Resp. ¶ 13.) Jacobs submitted a claim to Guardian for payment for the IMRT. (Pl. 56.1 Resp. ¶ 8; Def. 56.1 Resp. ¶ 13.)

1. March 29, 2006 Peer Review Report by MES Solutions

On March 29, 2006, MES Solutions ("MES"), a peer review agency, prepared a "Peer Review Report" examining whether IMRT could "be considered sufficiently investigated to show that IMRT is as effective as more standard radiation therapy treatments for [Jacobs'] diagnosis." (Pl. 56.1 Resp. ¶ 9; Def. 56.1 Exhibit 2, pp. 2-3.) After reviewing correspondence, claim forms, and clinical information, a peer review physician from MES, Dr. Harold E. Kim ("Dr. Kim"), rendered a report finding that "IMRT cannot be considered sufficiently investigated to show that IMRT is as effective as more standard radiation therapy treatments for metastatic cholangiocarcinoma." (Pl. 56.1 Resp. ¶ 9; Def. 56.1 Exhibit 2, p. 3.) Noting that no published reports of prospective randomized clinical studies involving IMRT existed at the time, Dr. Kim further concluded that there was a lack of information about clinical outcomes of IMRT for intrahepatic tumors. (Pl. 56.1 Resp. ¶ 9.) "Radiation therapy, including IMRT, to a primary tumor site," he noted, "cannot be considered a standard of care for stage IV cholangiocarcinoma with metastatic lesions to peritoneum and ribs." (Pl. 56.1 Resp. ¶ 9; Pl. 56.1 Exhibit 2, p. 265.) Finally, Dr. Kim stated that radiation therapy would at best provide local control at the primary site of the cancer, but that the local failure rate for bile duct cancer remains high in spite of radiation treatment. (Pl. 56.1 Resp. ¶ 9.) The MES Report identifies Dr. Kim as "Board Certified in Radiology" with a "Sub Speciality Certificate in Radiation Oncology." (Def. 56.1 Exhibit 2, p. 3).

2. March 29, 2006 Denial of Benefits Letters

On March 29, 2006, Guardian sent letters to MD Anderson denying Jacobs' IMRT claim and noting that MES's peer review physician had determined that IMRT was not sufficiently investigated to establish that it was more effective than standard radiation therapy. (Pl. 56.1 Resp. ¶ 10; Def. 56.1 Resp. ¶ 14.) The letters further explained that IMRT was not considered the standard of care for Jacobs' type of cancer. (Pl. 56.1 Resp. ¶ 10; Def. 56.1 Resp. ¶ 14.) The letters stated that Guardian's determination was based on a peer review report obtained from MES and that Anderson had the right to appeal this claim denial. (Pl. 56.1 Resp. ¶ 10; Def. 56.1 Resp. ¶ 14.) They did not, however, refer to any provision in the Policy requiring that medical treatment needs to be "more effective" than a "standard treatment" or meet any specific "standard of care." (Def. 56.1 Resp. ¶ 15.) The letters did not identify a specific internal rule, guideline, or protocol relied upon or present a detailed scientific or clinical basis for the determination. (Def. 56.1 Resp. ¶ 15; Am. Compl., Exhibit B.) One of the letters did, however, state that "[u][pon request the Clinical Review Criteria relied upon and all information pertaining to this determination is available." (Def. 56.1 Resp. ¶ 15; Am. Compl., Exhibit B.)

3. April 25, 2006 Appeal Letter by MD Anderson

MD Anderson sent a letter of appeal on behalf of Jacobs seeking reconsideration of Guardian's denial of benefits on April 25, 2006. (Pl. 56.1 Resp. ¶ 11.) In the letter, Jacobs' treating physician stated that IMRT was selected as the safest and most effective treatment for Jacobs because of the contours of his tumor and the way it was situated in relation to his adjacent organs. (Def. 56.1 Resp. ¶ 18.) The treating physician further opined that IMRT was necessary treatment for Jacobs' cancer. (Def. 56.1 Resp. ¶ 18.) The letter noted that "[i]n uncommon disease sites, it

will never be possible to demonstrate with adequate certainty in scientific studies that this methodology improves outcome." (Pl. 56.1 Resp. ¶ 11; Pl. 56.1 Exhibit 1, Exhibit C, p. 2.) It explains:

> [M]any insurance companies require evidence from well-controlled clinical trials published in peer-reviewed medical literature to support the non-investigational status of a medical service. [However,] this type of interpretation does not recognize the fact that the literature often lags at least one year behind the actual clinical practice and that for many medical services, these types of controlled studies may never be available. (Pl. 56.1 Resp. ¶ 11.)

On May 3, 2006, Guardian submitted MD Anderson's April 25, 2006 appeal letter and medical records regarding Jacobs' treatment to the Medical Review Institute of America, Inc. ("MRI"). (Pl. 56.1 Resp. ¶ 12.)[2] Guardian's May 3, 2006 letter to MRI stated in relevant part:

> A recent review showed that IMRT may not have sufficient scientific evidence to support it's [sic] use in some cancer diagnoses (including cholangiocarcinoma), may not be considered standard of care, and in selected instances is deemed investigational by some insurance plans. Following an independent physician consultant view of records submitted by MD Anderson, the radiation services were

[2] Jacobs objects to all statements of fact supported by documents attached to the Affidavit of Sharon Dash for lack of first-hand knowledge under Federal Rule of Evidence 602 and lack of proper authentication under Federal Rule of Evidence 901. (*See, e.g.*, Pl. 56.1 Resp. ¶¶ 12, 14, 17, 20, 22, 24-25.) "The Federal Rules of Evidence, however, do not apply to an ERISA administrator's benefits determination, and we review the entire administrative record." *Black v. Long Term Disability Ins.*, 582 F.3d 738, 746 n.3 (7th Cir. 2009). Moreover, even under the Federal Rules of Evidence these documents would be admissible. Under Federal Rule of Evidence 602, "[a] witness may not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may, but need not, consist of the witness' own testimony." F.R.E. 502. Here, Dash's personal knowledge of the contents of these documents is supported by the testimony in her affidavit stating that: "I, Sharon Dash . . . state that I am fully familiar with the facts set forth herein." (Def. 56.1 Exhibit 3, p. 1.) Moreover, a document may be authenticated under Federal Rule of Evidence 901(b)(1) through "testimony of witness with knowledge . . . that a matter is what it is claimed to be." Fed. R. Evid. 901(b)(1). Dash's affidavit further states that "[t]he documents attached to my affidavit as Exhibit A were either sent to or received by The Guardian in connection with administering benefit claims submitted by William Jacobs." (Def. 56.1 Exhibit 3, p. 1.) Thus, Dash's affidavit establishes personal knowledge and serves as appropriate authentication under the Federal Rules of Evidence for the documents attached to her affidavit. *See Article II Gun Shop, Inc. v. Gonzales*, 441 F.3d 492, 496 (7th Cir. 2006) (finding that district court properly considered reports on motion for summary judgment where "the reports were authenticated by [an agent's] affidavit; the reports were attached to his affidavit, which met the requirements of Rule 56(e); and [the agent] is a person through whom the reports could be admitted into evidence, because he is an agent of ATF and is knowledgeable about ATF's recordkeeping system").

> denied as of being a covered benefit under the member's plan. MD Anderson has appealed this decision.

(Def. 56.1 Resp. ¶ 20.)

4. May 11, 2006 Peer Review Report by MRI

MRI submitted a peer review report to Guardian on May 11, 2006 concluding that there were still no data to support the efficacy of radiation therapy—either standard or IMRT therapy—for the treatment of metastatic cholangiocarcinoma, except for symptom control of isolated legions. (Pl. 56.1 Resp. ¶ 12.) "In the most current edition of the NCCN Clinical Guidelines for Hepatobiliary Cancers," MRI's report noted, "radiation therapy is not indicated as an acceptable option for management of metastatic intrahepatic cholangiocarcinoma except as might be needed for comfort care." (Pl. 56.1 Resp. ¶ 12.) Additionally, the report stated that there were "insufficient data of high enough quality . . . to establish a useful consensus or standard of care. The literature on IMRT for this particular diagnosis is sparse and represents a limited number of patients in studies of poor quality concentrating mainly on technical feasibility and safety; IMRT cannot be considered 'sufficiently investigated' to establish its usefulness." (Pl. 56.1 Resp. ¶ 12.) Although the report indicates that among the records reviewed was MD Anderson's appeal letter, MRI did not directly address the statement in the letter that Jacobs' treating physician found IMRT to be efficacious and medically necessary for Jacobs. (Def. 56.1 Resp. ¶ 22; Pl. 56.1 Exhibit 7.) According to the report, the physician who conducted the review underlying MRI's report had been in practice since 1978 and was certified by the American Board of Radiology with a subspecialty in Therapeutic Radiology. (Pl. 56.1 Resp. ¶ 12.) He also served as Medical Director of Radiation and Associate Professor of Radiology at a medical school in the United States and as Chairman of the Board of Trustees for a local medical association. (Pl. 56.1 Resp. ¶ 12.)

5. July 24, 2006 Denial of Benefits Letter

On July 24, 2006, Guardian denied Jacobs' appeal, claiming that IMRT was "not sufficiently investigated to show that it is more effective than standard radiation therapy and that the treatment is not considered standard of care." (Def. 56.1 Resp. ¶ 19.) Although Guardian stated that its determination was based on the opinion of a "second independent physician consultant," it did not identify the consultant in the letter. (Def. 56.1 Resp. ¶ 19.) The "second independent physician consultant" referred to in Guardian's July 24, 2006 letter denying benefits is MRI. (Def. 56.1 Resp. ¶ 20.) In denying Jacobs' benefits, Guardian explained that it was relying on MRI's evaluation of whether IMRT proved efficacious for treatment of Jacobs' type of cancer and not whether it proved efficacious for treatment of Jacobs himself. (Def. 56.1 Resp. ¶ 22.) Guardian's letter did not point to any specific provision in the Policy requiring that the treatment prescribed as medically necessary be more effective than the standard treatment, but did state that "[u]pon request the Clinical Review Criteria relied upon and all information pertaining to this determination is available." (Def. 56.1 Resp. ¶ 19; Am. Compl., Exhibit D.)

B. Chemotherapy

Since 2007, Jacobs' treatment has included chemotherapy with: (1) a combination of the drugs Avastin and Abraxane; (2) a single use of either Avastin; (3) a singe use of Abraxane; or (4) a combination of the drugs Abraxane and Irinotecan. (Def. 56.1 Resp. ¶ 23.) Jacobs' treating physician has treated and is treating Jacobs with drugs that have been used for similar cancers based on his medical judgment given the molecular characteristics of Jacobs' tumor. (Def. 56.1 Resp. ¶ 23.) Guardian has never consulted with Jacobs' treating physician personally about the

chemotherapy prescribed for his cancer, but instead has denied him benefits based on the reviews it requests and receives from independent peer review physicians. (Def. 56.1 Resp. ¶ 24.)

1. November 13, 2007 Peer Review Report by MRI

On August 21, 2007, Jacobs' treating physician began treating him with the combination regimen of Avastin and Abraxane and Jacobs subsequently submitted a claim for benefits. (Pl. 56.1 Resp. ¶ 14.) MRI submitted an "independent peer review" of this claim to Guardian on November 13, 2007. (Def. 56.1 Resp. ¶ 26; Pl. 56.1 Resp. ¶ 14.) Guardian provided Jacobs' treating records to MRI for purposes of this review but did not provide a narrative statement or description from his treating physician as to the efficacy of a combination of Abraxane and Avastin for his type of cancer. (Def. 56.1 Resp. ¶ 28.) In MRI's review, the peer review physician stated that "the preferred approach to biliary obstruction is percutaneous transphepatic radiologic catheter bypass or endoscopically placed stents" and that "[s]tandard chemotherapy is usually not effective, though occasional patients might be palliated." (Pl. 56.1 Resp. ¶ 14; Def. 56.1 Exhibit 3, Ex. A pp. 6-7.) The physician noted that "[a] search in the PDQ [National Cancer Institute's Physician Data Query] website entered both drug names showed 4 clinical trials for Avastin, none for Abraxane and none for the combination of both drugs." (Pl. 56.1 Resp. ¶ 14.) The physician concluded that "Abraxane and Avastin are not considered medically necessary for the treatment of this condition in this particular setting." (Pl. 56.1 Resp. ¶ 14.) According to MRI's review, the peer review physician was board certified in internal medicine by the American Board of Internal Medicine, Hematology and Medical Oncology and was a member of the American Society of Clinical Oncology and the American Society of Hematology. (Pl. 56.1 Resp. ¶ 14.)

2. November 21, 2007 Denial of Benefits Letter

Guardian sent a letter to Jacobs on November 21, 2007 denying benefits for the Avastin and Abraxane regimen and noting that there were no approved clinical trials testing the use of an Avastin and Abraxane combination for his diagnosis. (Pl. 56.1 Resp. ¶ 15; Def. 56.1 Resp. ¶ 25.) The letter further informed Jacobs that an independent peer reviewer had concluded that that this combination was experimental and not medically necessary, but did not provide the identity of that reviewer. (Pl. 56.1 Resp. ¶ 15; Def. 56.1 Resp. ¶ 25.) The letter explained that "[e]xperimental treatment and those determined to not be medically necessary are not a covered benefit under your plan." (Def. 56.1 Resp. ¶ 25; Amend. Compt., Exhibit E.) The letter informed Jacobs that he had a right to appeal the claim denial and should submit any supporting documentation with his appeal. (Pl. 56.1 Resp. ¶ 15.) Finally, the letter specified that "[u]pon request and free of charge you are entitled to receive . . . copies of . . . guidelines, documents, records, clinical review criteria and all other information pertaining to this determination." (Pl. 56.1 Resp. ¶ 15; Amend. Compt., Exhibit E.) Neither Guardian nor MRI consulted with Jacobs' treating physician about the medical necessity or experimental nature of the Abraxane and Avastin treatment. (Def. 56.1 Resp. ¶ 28.)

3. December 7, 2007 Peer Review Report by MCMC

On December 7, 2007, Guardian sought an additional review of the Abraxane and Avastin regimen from MCMC, a peer review analysis company. (Pl. 56.1 Resp. ¶ 16; Def. 56.1 Resp. ¶ 30.) Dr. Sujith R. Kalmadi ("Dr. Kalmadi"), a board certified specialist in Internal Medicine—Medical Oncology, performed the review. Dr. Kalmadi concluded that:

> The use of Abraxane/Avastin is not being provided as part of an approved clinical trial. This is being provided as off label use of these drugs . . . . Given the member's diagnosis the use of Abraxane and Avastin is an investigational cancer treatment. It does not have approval by the Food and Drug Administration (FDA), compendium listed, randomized control trials, or expert consensus . . . . The use of Abraxane and

> Avastin is not medically necessary for this member, as this has not been shown to be beneficial in randomized control trials.

(Pl. 56.1 Resp. ¶ 16.) The report further stated that this particular combination has not been shown beneficial in any published peer review literature of clinical trials. (Pl. 56.1 Resp. ¶ 16.) Guardian then continued to deny Jacobs' claims involving the combination of Abraxane and Avastin, explaining that MCMC maintained that they were not part of a clinical trial and thus were considered investigational and not medically necessary. (Def. 56.1 Resp. ¶ 31.)

4. December 26, 2007 Appeal Letter by University Medical Center

The University Medical Center in Tuscon sent an appeal letter on behalf of Jacobs on December 26, 2007, enclosing Jacobs' medical records, literature in support of his treatment regimens, and a copy of an email from Tomislav Dragovich ("Dragovich") to Wendalyn Andrews ("Andrews"), the Director of Oncology Services at the University Medical Center. (Pl. 56.1 Resp. ¶ 17.) In that email, Dragovich stated: "there is not much, a case report and phase I study. I think the driving point should be that beyond [sic] there are no approved and known effective treatments for this disease and he is still strong to tolerate therapy and he is responding to this therapy." (Pl. 56.1 Resp. ¶ 17; Def. 56.1, Exhibit 3, Ex. A, p. 13.)

5. January 15, 2008 Peer Review Report by MCMC

On January 15, 2008, Guardian sought an appeal review by MCMC, and Dr. Robert Marciniak ("Dr. Marciniak"), who is M.D. board certified in internal medicine and medical oncology, reviewed the documents submitted. (Pl. 56.1 Resp. ¶ 18; Def. 56.1 Resp. ¶ 30.) He concluded that because "there are no peer-reviewed published clinical studies of the combination of Abraxane/Avastin as a treatment for advanced cholangiocarcinoma, . . . it would be considered investigational and of unproved benefit. As it is of unproven benefit, it would not be considered

medically necessary for this patient." (Pl. 56.1 Resp. ¶ 18; Def. 56.1 Exhibit 3, Ex. A, p. 15.) Dr. Marciniak noted that there were no studies of Avastin or Abraxane as monotherapy for cholangiocarcinoma and that the reference provided by Jacobs' treating physician was not a trial of Abraxane and Avastin, but was a phase I trial of Abraxane and Carboplatin. (Pl. 56.1 Resp. ¶ 18.) The materials provided to MCMC reviewers did not include any statements from Jacobs' treating physician about the efficacy of the treatment of Abraxane and Avastin being provided to Jacobs. (Def. 56.1 Resp. ¶ 30; Pl. 56.1 Exhibit 3; p.135: 9-16.)

6. June 2, 2008 Request for Reconsideration

On June 2, 2008, Jacobs' treating physician wrote to Guardian requesting that it reconsider its decision to deny coverage, explaining that under the Avastin and Abraxane treatment, Jacobs had experienced an objective and sustained tumor response with tumor marker reduction and PET-CT improvement. (Def. 56.1 Resp. ¶ 32.) The letter further stated that the treatment regimen had been beneficial to Jacobs. (Def. 56.1 Resp. ¶ 32.)

7. September 30, 2008 and December 4, 2008 Denial of Benefits Letters

On September 30, 2008 and December 4, 2008, Guardian again denied coverage for Jacobs' treatment, explaining that an "independent physician consultant determined that treatment with Abraxane plus Avastin was not provided as part of an approved clinical trial, would be considered an investigational treatment for the member's diagnosis and would not be considered medically necessary for this member." (Def. 56.1 Resp. ¶ 33.) These denials were based on the November 13, 2007, December 7, 2007, and January 15, 2008 reviews that Guardian requested from its independent reviewers. (Def. 56.1 Resp. ¶ 34.) In its September 30, 2008 and December 4, 2008 letters denying coverage, Guardian did not respond to many of the specific concerns voiced in the

letter of Jacobs' treating physician. (Def. 56.1 Resp. ¶ 33.) The letters also did not identify any specific Policy provision, internal rule, guideline or protocol relied upon in denying the claims. (Def. 56.1 Resp. ¶ 34.) The letters, however, stated that "[u]pon request and free of charge you are entitled to receive reasonable access to, and copies of, these guidelines, documents, records, clinical review criteria and all other information pertaining to this determination." (Def. 56.1 Resp. ¶ 34; Amend. Cmplt, Exhibit G.)

8. January 19, 2009 Peer Review Report by MRI

In September 2008, Jacobs' treating physician began treating him with chemotherapy consisting of a single use of Avastin or Abraxane and Jacobs submitted those claims to Guardian. (Def. 56.1 Resp. ¶ 35.) On January 19, 2009, MRI sent Guardian an independent peer review report about the status of a single use of Avastin as a treatment regimen for Jacobs' cancer. (Pl. 56.1 Resp. ¶ 20.) The physician who conducted the review was Acting Chief of Hematology/Oncology at a university hospital, board certified in oncology and hematology, and a member of the American Society of Clinical Oncology. (Pl. 56.1 Resp. ¶ 20.) The peer review physician concluded in that report that the use of Avastin was not medically necessary because no credible medical literature showed that a second line chemotherapy or maintenance treatment would be beneficial for the treatment of Jacobs' cancer. (Pl. 56.1 Resp. ¶ 20.) Although the physician stated that Avastin is being studied in various phase II studies, the report concluded that as of yet there was no confirmation that it could be considered medically necessary or beneficial. (Pl. 56.1 Resp. ¶ 20; Def. 56.1 Resp. ¶ 36.) The report failed to identify by name the individual who reviewed Jacobs' claim. (Def. 56.1 Resp. ¶ 36.)

9. January 22, 2009 Denial of Benefits Letter

On January 22, 2009, Guardian informed Jacobs of this conclusion by letter. (Pl. 56.1 Resp. ¶ 21; Def. 56.1 Resp. ¶ 36.) The letter did not: (1) identify the name or credentials of the MRI consultant; (2) identify any specific internal rule, guideline or protocol relied upon in denying the claim; (3) identify a specific Policy provision upon which the denial was based; or (4) provide an explanation of the scientific or clinical bases for the determination that the use of Avastin was not medically necessary. (Def. 56.1 Resp. ¶ 36.) The letter explained that Jacobs was entitled to receive, free of charge, copies of guidelines, documents, records, scientific or clinical review criteria, and all other information pertaining to the claim determination upon request. (Def. 56.1 Resp. ¶ 36.)

10. May 11, 2009 Peer Review Report by MRI

On May 11, 2009, after Jacobs began treatment with a single use of Abraxane, MRI sent another independent peer review report to Guardian about the regimen of single agent Abraxane. (Pl. 56.1 Resp. ¶ 22.) The peer review physician from MRI who performed the review was board certified in internal medicine with a subspecialty in medical oncology, was a member of the American Society of Clinical Oncology, and taught gastrointestinal oncology at a cancer center. (Pl. 56.1 Resp. ¶ 22.) The physician concluded that the use of singe agent Abraxane could not be considered medically necessary for a patient with advanced cholangiocarcinoma. (Pl. 56.1 Resp. ¶ 22.) The physician further considered whether the combination of Abraxane and Avastin was a medically necessary treatment and concluded that it was not. (Def. 56.1 Resp. ¶ 37.) The report did not identify the physician by name. (Def. 56.1 Resp. ¶ 37.)

11. May 12, 2009 Denial of Benefits Letter

On May 12, 2009, Guardian again informed Jacobs by letter that they were denying benefits for the Abraxane treatment because it was not considered medically necessary for his type of cancer. (Pl. 56.1 Resp. ¶ 23.) Similar to the January letter, this letter did not: (1) identify the name or credentials of the MRI consultant; (2) identify any specific internal rule, guideline or protocol relied upon in denying the claim; (3) identify a specific Policy provision upon which the denial was based; or (4) provide an explanation of the scientific or clinical bases for the determination that the use of Abraxane was not medically necessary. (Def. 56.1 Resp. ¶ 37.) Again, the letter explained that Jacobs was entitled to receive, free of charge, copies of guidelines, documents, records, scientific or clinical review criteria, and all other information pertaining to the claim determination upon request. (Def. 56.1 Resp. ¶ 37.)

12. August 28, 2009 Peer Review Report by MRI

Jacobs' treating physician next began using a combination of Abraxane and Irinotecan to treat Jacobs' cancer, and Guardian submitted medical records associated with his treatment to MRI for another independent peer review. (Pl. 56.1 Resp. ¶ 24.) The peer review physician stated in his August 28, 2009 report that although chemotherapy can be used to treat this type of cancer, it is not particularly effective. (Pl. 56.1 Resp. ¶ 24.) The report further explained that:

> There is no combination that has been proven to be more effective than another. There is no credible medical literature that second line chemo is beneficial in gallbladder cancer . . . . It is unproven to continue Avastin past progression . . . The continuation of [Abraxane] through consecutive lines of therapy after progression is highly experimental.

(Pl. 56.1 Resp. ¶ 24.) According to the report, the physician who performed the review was board certified in internal medicine with subspecialties in oncology and hematology, Acting Chief of

Hematology/Oncology at a university hospital, and also a member of the American Society of Clinical Oncology. (Pl. 56.1 Resp. ¶ 24.)

13. August 31, 2009 Denial of Benefits Letter

On August 31, 2009, Guardian sent a letter to Jacobs informing him that it had reviewed the treatment regimen of Abraxane combined with Irinotecan, and an independent peer review physician had determined that the combination was not guideline-recommended for Jacobs' cancer type and that no independent studies supported its use. (Pl. 56.1 Resp. ¶ 25.)

C. Guardian's Knowledge Pertaining to the Peer Review Reports

With respect to MES's March 29, 2006 Peer Review Report, MRI's May 11, 2006 Peer Review Report, MRI's November 13, 2007 Peer Review Report, and MCMC's January 15, 2008 Peer Review Report, Guardian's Rule 30(b)(6) designee Sharon Dash ("Dash") does not have information about how Guardian selected each reviewer to provide medical review services, the professional qualifications of the review service, or the qualifications, backgrounds, and procedures followed by the peer review physicians performing the reviews beyond "what is indicated on the actual review[s]." (Def. 56.1 Resp. ¶ 16; Def. 56.1 Resp. ¶ 17; Pl. 56.1, Exhibit 3; p.103: 13-17; Def. 56.1 Resp. ¶ 21; Pl. 56.1 Exhibit 3; p.103: 13-17; Def. 56.1 Resp. ¶ 27; Pl. 56.1, Exhibit 3; p.103: 13-17; Def. 56.1 Resp. ¶ 30; Pl. 56.1, Exhibit 3; p.103: 13-17.) Guardian recognizes that the review process is subjective and that it could have received an entirely different recommendation from another reviewer. (Def. 56.1 Resp. ¶ 22.)

II. Relevant Policy Language

Under the terms of the Policy, medical services are (i) covered; (ii) covered with special limitations; or (iii) excluded. (Def. 56.1 Resp. Add. Facts ¶ 2.) Both the "Exclusions" section of

the Policy and the definition of "Covered Charges" in the Policy's Glossary state that Guardian does not pay for services and supplies that are not:

> (a) furnished or ordered by a recognized provider; (b) medically necessary to diagnose or treat a *sickness* or *injury*; (c) accepted by a professional medical society in the United States as beneficial for the control or cure of the *sickness* or *injury* being treated; and (d) furnished within the framework of generally accepted methods of medical management currently used in the United States.

(Pl. 56.1 Resp. ¶ 5; Am. Compl. Exhibit A, p. 102). The definition of "Covered Charges" in the Glossary further explains: "Subject to all of the terms of this *plan*, we pay benefits for *covered charges* incurred by a *covered person* while he is insured by this *plan*. Read the entire *plan* to find out what we limit or exclude." (Am. Compl. Exhibit A, p. 102.) Similarly, the first line of the "Covered Charges" section of the Policy reads: "This section lists the types of charges we cover. But what we pay is subject to all the terms of this *plan*. Read the entire *plan* to find out what we limit or exclude." (Am. Compl. Exhibit A, p. 68.)

The "Exclusions" section of the Policy further states: "We don't pay for *experimental treatment*." (Pl. 56.1 Resp. ¶ 5). "Experimental treatment" is defined as treatment:

> (a) that has not been scientifically proven or fully developed; (b) cannot be supported in medical literature published by a professional medical society in the United States; (c) is not accepted by a professional medical society in the United States as beneficial for the control or cure of *sickness* or *injury* being treated; or (d) is not furnished within the framework of generally accepted methods of medical management currently being used in the United States.

(Pl. 56.1 Resp. ¶ 6).

Among the items listed in the "Covered Charges" section of the Policy under "Other Covered Medical Services and Supplies" are "anesthetics and their administration; inhalation therapy; hemodialysis; radiation and chemotherapy; physical therapy by a licensed physical therapist; casts; splints; and surgical dressings." (Def. 56.1 Resp. ¶ 5.) The section of the Policy

entitled "Covered Charges with Special Limitations" limits charges associated with "investigational cancer treatments," but agrees to cover charges for routine patient care in connection with investigational cancer treatment in an approved cancer research trial. (Def. 56.1 Resp. Add. Facts ¶ 3.) This care is limited under the Policy, however, to care that is: (1) medically necessary; and (2) for a covered person who has been diagnosed by his or her doctor with a life-threatening terminal illness related to cancer. (Def. 56.1 Resp. Add. Facts ¶ 3.)

III. Claims Handling Procedures

When Guardian receives a claim for medical benefits pursuant to the Policy, that claim is assigned to a particular unit and individual based on the dollar amount of the claim. (Def. 56.1 Resp. ¶ 7.) The individual who initially makes the determination of whether to pay or deny the claim does not need to be medically trained. (Def. 56.1 Resp. ¶ 7; Pl. 56.1 Exhibit 3, pp.59:22-60:8.) Under the terms of the Policy, in the event that Guardian denies a claim it must provide the claimant a notice that sets forth, among other things: (1) the specific reason for the adverse determination; (2) reference to the specific plan provision on which the determination is based; (3) "identification and description of any specific internal rule, guideline or protocol that was relied upon in making an adverse benefit determination, or a statement that a copy of such information will be provided to the claimant free of charge upon request"; and (4) "in the case of an adverse benefit determination based on medical necessity or experimental treatment, notice will either include an explanation of the scientific or clinical basis for the determination, or a statement that such explanation will be provided free of charge upon request." (Def. 56.1 Resp. ¶ 8; Am. Compl., Exhibit A, p. 116.)

When Guardian decides to deny a claim based on lack of medical necessity, a Guardian employee sends that claim to one of many independent medical reviewers. (Def. 56.1 Resp. ¶ 8.)

Guardian retains and compensates those reviewers. (Def. 56.1 Resp. ¶ 8.) Dash does not know, however: (1) how much the reviewers are compensated; (2) their annual revenue received for services provided to Guardian; (3) how many claims Guardian submits to them; (4) how often they concur with Guardian's decision to deny a claim; and (5) their process for employing reviewers. (Def. 56.1 Resp. ¶ 8.)

The Policy provides that "Guardian is the Claims Fiduciary with discretionary authority to determine eligibility for benefits and to construe the terms of the plan with respect to claims," and must do so "prudently and in the interest of plan participants and beneficiaries." (Def. 56.1 Resp. ¶ 6; Pl. 56.1 Resp. ¶ 7.) It is Guardian's position that "if the combination of drugs are not the subject of a clinical trial or a specific FDA approval for the particular condition at issue, then it is within Guardian's purview to deny the claim without further information"—including whether the patient's treating physician believes that the efficacy of that combination of drugs has improved the patient's condition or kept the patient alive. (Def. 56.1 Resp. ¶ 29; Pl. 56.1, Exhibit 3, pp. 117: 20-118: 13.)

Under the Policy, a claimant has the right to appeal a denial of benefits. (Def. 56.1 Resp. ¶ 10.) In reviewing such an appeal, Guardian must:

> provide for a review conducted by a named fiduciary who is neither the person who made the initial adverse determination nor that person's subordinate;
>
> in deciding an appeal based upon a medical judgment, consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment;
>
> identify medical or vocational experts whose advice was obtained in connection with an adverse benefit determination; and
>
> ensure that a health care professional engaged for consultation regarding an appeal based upon a medical judgment shall be neither the person who was consulting in connection with the adverse benefit determination, nor that person's substitute.

(Def. 56.1 Resp. ¶ 10.)

STANDARD OF REVIEW

On cross-motions for summary judgment, each movant must satisfy the requirements of Federal Rule of Civil Procedure 56. *See Cont'l Cos. Co. v. Nw. Nat'l Ins. Co.*, 427 F.3d 1038, 1041 (7th Cir. 2005). Summary judgment is proper when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In determining whether a genuine issue of material fact exists, the Court must view the evidence and draw all reasonable inferences in favor of the party opposing the motion. *See Bennington v. Caterpillar Inc.*, 275 F.3d 654, 658 (7th Cir. 2001); see *also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). However, the Court will "limit its analysis of the facts on summary judgment to evidence that is properly identified and supported in the parties' [Local Rule 56.1] statement." *Bordelon v. Chi. Sch. Reform Bd. of Trs.*, 233 F.3d 524, 529 (7th Cir. 2000). Where a proposed statement of fact is supported by the record and not adequately rebutted, the court will accept that statement as true for purposes of summary judgment. An adequate rebuttal requires a citation to specific support in the record; an unsubstantiated denial is not adequate. *See Albiero v. City of Kankakee*, 246 F.3d 927, 933 (7th Cir. 2001); *Drake v. Minn. Mining & Mfg. Co.*, 134 F.3d 878, 887 (7th Cir. 1998) ("'Rule 56 demands something more specific than the bald assertion of the general truth of a particular matter[;] rather it requires affidavits that cite specific concrete facts establishing the existence of the truth of the matter asserted.'").

A denial of insurance benefits is reviewed de novo under ERISA "unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or

to construe the terms of the plan." *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 114-15 (1989). When the plan gives the administrator discretionary authority, the Court applies an "arbitrary and capricious" standard of review. *See Hess v. Reg-Ellen Mach. Tool Corp. Employee Stock Ownership Plan*, 502 F.3d 725, 727 (7th Cir. 2007). Here, the Policy states that "Guardian is the Claims Fiduciary with discretionary authority to determine eligibility for benefits and to construe the terms of the plan with respect to claims," echoing precisely the language set forth in *Firestone*, 489 U.S. at 114-15. The parties agree that this provision imparts Guardian with discretionary authority and the arbitrary and capricious standard applies. (*See* R. 43, p. 11; R. 46, p. 10.) As such, the Court reviews Defendants' denials of Jacobs' claims using the arbitrary and capricious standard.

The Court's review under this standard is deferential. *See Firestone*, 489 U.S. at 111. "An administrator's decision will not be overturned unless it is downright unreasonable." *Davis v. Unum Life Ins. Co. of Am.*, 444 F.3d 569, 576 (7th Cir. 2006). In other words, the Court will "uphold the plan's decision as long as (1) it is possible to offer a reasoned explanation, based on the evidence, for a particular outcome, (2) the decision is based on a reasonable explanation of relevant plan documents, or (3) the administrator has based its decision on a consideration of the relevant factors that encompass the important aspects of the problem." *Sisto v. Ameritech Sickness & Accident Disability Ben. Plan*, 429 F.3d 698, 700 (7th Cir. 2005).

The Supreme Court's decision in *Metropolitan Life Insurance v. Glenn*, 554 U.S. 105 (2008), imposes one additional consideration in cases where "responsibility for both claim determinations and pay-outs is vested in the same entity." *See Leger v. Tribune Co. Long Term Disability Ben. Plan*, 557 F.3d 823, 831 (7th Cir. 2009). In such cases, "the court is required to take such an

obvious conflict of interest into consideration." *See id.* Here, it is undisputed by the parties that Guardian insured the Policy, processed claims under the Policy, and made determinations of benefits eligibility under the Policy. Thus, even though "the correct standard of review to be applied . . . remains the arbitrary and capricious standard, . . . one of the factors that must be taken into account in applying that standard is any conflict of interest." *See Fischer v. Liberty Life Assur. Co. of Boston*, 576 F.3d 369, 375 (7th Cir. 2009). The presence of a conflict will "act as a tiebreaker when [] other factors are closely balanced," but does not play "an important role" in non-borderline cases. *See id.* at 377.

DISCUSSION

I. Defendants' Motion for Leave to File Supplemental Authority

As an initial matter, after the parties completed their summary judgment briefing in this case, Defendants filed a Motion for Leave to File Supplemental Authority addressing the applicability of the Federal Rules of Evidence to a court's review of an ERISA Plan claim denial. On January 28, 2010, the Court granted Defendants' Motion for Leave to File Supplemental Authority and took Jacobs' Response to the Motion for Leave to File Supplemental Authority under advisement. (*See* R. 63.) The supplemental authority at issue is the Seventh Circuit decision in *Black v. Long Term Disability Ins.*, 582 F.3d 738 (7th Cir. 2009). Jacobs' Response argues both that Defendants should have filed this authority in their original summary judgment briefing because it was decided prior to that briefing, and that *Black*, 582 F.3d 738, is distinguishable from this case and does not contain any new, relevant propositions of law.

Although *Black* was decided several months before the parties filed their cross-motions for summary judgment and Defendants could have cited it at that time, there is no prejudice to Jacobs

resulting from this supplemental briefing. The Court would have addressed the relevant law even if the parties failed to do so. Here, both sides have had a chance to address the law and therefore the objection on this ground is denied.

Jacobs also argues in his Response that "Guardian contends that *Black* supposedly refutes Jacobs' argument that the independent medical reviews Guardian relied on lack a proper foundation. Jacobs, however, never made such an argument." (R. 62, p. 2.) As explained in footnote 2 *infra*, however, in Jacobs' Response to Defendants' Rule 56.1 Statements of Fact he objects to all statements of fact supported by documents attached to the Affidavit of Sharon Dash for lack of first-hand knowledge under Federal Rule of Evidence 602 and lack of proper authentication under Federal Rule of Evidence 901. (*See, e.g.*, Pl. 56.1 Resp. ¶¶ 12, 14, 17, 20, 22, 24-25.) In *Black*, the plaintiff similarly argued that the court "should discount all of the consulting physicians' reports for their lack of first-hand clinical knowledge in accordance with Federal Rules of Evidence 602 and 802." *See* 582 F.3d at 746 n.3. The court rejected this argument, explaining that "[t]he Federal Rules of Evidence . . . do not apply to an ERISA administrator's benefits determination, and we review the entire administrative record." *Id.* Thus, *Black* is directly relevant to Jacobs' objection to the documents attached to Dash's affidavit, as discussed in footnote 2 *infra*. *See id.*

Jacobs devotes the remainder of his Response to making broad distinctions between the facts in this case and the facts in *Black*, *see id.* Defendants' motion, however, merely seeks to draw to the Court's attention the narrow point of relevant law discussed in footnote 2 *infra*. (*See* R. 62). Because the Court finds the supplemental authority helpful with respect to this point of law, it grants Defendants' Motion for Leave to File Supplemental Authority. *See, e.g.*, *People of Ill. Ex rel. Madigan v. Hemi Group, LLC*, No. 08-3050, 2008 WL 4545349, at *3, n. 1 (C.D. Ill., October 10,

2008) (Scott, J.) (granting a Motion for Leave to File Supplemental Authority "[b]ecause the case [wa]s helpful").

II. Cross-Motions for Summary Judgment

As an initial matter, Jacobs' First Amended Complaint alleges claims under 29 U.S.C. § 1132(a)(1)(B) for arbitrary and capricious denial of benefits (Count I) and under 29 U.S.C. § 1132(a)(3) for breach of fiduciary duty through the arbitrary and capricious denial of benefits (Count II). (*See* R. 23.) Under ERISA, a breach of fiduciary duty claim to recover for injuries caused to an individual, and not the Plan as a whole, must be brought under § 1132(a)(3) of ERISA. *See Kenseth v. Dean Health Plan, Inc.*, 2010 WL 2557767, at *23 (7th Cir. June 28, 2010). "A denial-of-benefits claim," however, "may only be pursued under section § 1132(a)(1)(B)" and *not* under § 1132(a)(3). *See id.* at *24 (citing *Varity Corp. v. Howe*, 516 U.S. 489, 515 (1996)). Thus, "[n]otwithstanding the obstacles to relief under section 1132(a)(1)(B), [a plaintiff] may not obtain comparable relief under the guise of a claim for breach of fiduciary duty" pursuant to § 1132(a)(3). *See id.* Here, Jacobs' breach of fiduciary duty claim is premised only on Defendants' "den[ial of] coverage under the Plan and Policy in a manner that was arbitrary and capricious"–in other words, the same premise as his § 1132(a)(1)(B) denial-of-benefits claim. (*See* R. 23, pp. 13-15) Moreover, his First Amended Complaint seeks the same relief for the § 1132(a)(3) claim in Count II and the § 1132(a)(1)(B) claim in Count I. (*See* R. 23, pp. 12-15.) Even though the parties do not address breach of fiduciary duty separately in their briefs, the Court clarifies that Jacobs' breach of fiduciary duty claim based on the arbitrary and capricious denial of benefits cannot stand. *See Kenseth*, 2010 WL 2557767, at *23-24. The Court, therefore, analyzes his claim for denial of benefits pursuant to § 1132(a)(1)(B). *See id.*; *see also, e.g., Schultz v. Prudential Ins. Co. of Am.*, 678 F.Supp.2d 771,

778 -779 (N.D. Ill. 2010) (finding that "it must dismiss Schultz's Section 1132(a)(3) claim if adequate relief for her alleged injury is available under Section 1132(a)(1)(B)");*Ogden v. Blue Bell Creameries U.S.A., Inc.*, 348 F.3d 1284, 1287-88 (11th Cir. 2003) (stating that an ERISA plaintiff who has an adequate remedy under Section 1132(a)(1)(B) cannot alternatively plead and proceed on a claim for breach of fiduciary duty under Section 1132(a)(3)).

Turning to the substance of the parties' motions, Jacobs alleges that Defendants' adverse benefits determinations were both procedurally and substantively arbitrary and capricious. He asserts that Defendants failed to provide him with a full and fair review of his claim, as required by 29 U.S.C. § 1133 ("§ 1133") of ERISA and the accompanying regulations. He also contends that Defendants arbitrarily and capriciously: (1) denied his claims even though chemotherapy and radiation treatments are listed under the "covered" section of the Policy, (2) failed to adequately consider the opinion of Jacobs' treating physician about the efficacy of the treatments used; (3) relied on the reports by independent peer review physicians without adequate information about them; and (4) operated under a conflict of interest. Defendants respond that they substantially complied with the procedural requirements under ERISA and reasonably determined that each of Jacobs' treatments qualified as experimental or not medically necessary under the Policy.

A. Defendants' Compliance with ERISA's Procedural Requirements

Because a finding that Defendants failed to comply with § 1133 may preclude a substantive review of its denial of benefits, the Court first considers Jacobs' argument that Defendants failed to comply with ERISA's procedural requirements. *See, e.g.*, *Halpin v. Grainger, Inc.*, 962 F.2d 685, 697 (7th Cir. 1992) (first addressing an insurer's compliance with the statutory requirements under § 1133 and finding that the insurer's "failure to set out its reasoning" in compliance with § 1133

"makes any such [substantive] review" of the claim denial "impossible"); *Sven v. Principal Mutual Life Ins. Co.*, No. 95-5232, 1996 WL 539109 (N.D. Ill. Sept. 20, 1996) (Kocoras, J.) (first addressing the argument that an insurer failed to comply with its obligations under § 1133 because "the finding by a court that an insurer has violated § 1133 may preclude any substantive review of the denial").

Although claimants are entitled to full and fair review of their claims under ERISA, strict compliance with § 1133 and the accompanying regulations is not required; instead, "substantial compliance is sufficient." See *Halpin*, 962 F.2d at 690. In order to achieve substantial compliance, the plan must supply the beneficiary with "a statement of reasons that, under the circumstances of the case, permits a sufficiently clear understanding of the administrator's position to permit effective review." *See id.* Thus, even where the Court finds that an insurer's communications "did not comply with the regulations, [its] inquiry is not at an end"--it must assess whether the insurer substantially complied in a way that allows the court to meaningfully review its decision. *See id.* at 693-94.

1. Notice Requirements

Jacobs first contends that the explanations provided in his denial letters did not comply with ERISA's procedural notice requirements. ERISA sets forth "certain minimum requirements for procedures and notification when a plan administrator denies a claim for benefits. In a nutshell, ERISA requires that specific reasons for denial be communicated to the claimant and that the claimant be afforded an opportunity for 'full and fair review' by the administrator." *Id.* at 688 (quoting 29 U.S.C. § 1133); *see also Love v. National City Corp. Welfare Ben. Plan*, 574 F.3d 392, 396 (7th Cir. 2009); *Hackett v. Xerox Corp. Long-Term Disability Income Plan*, 315 F.3d 771, 775 (7th Cir. 2003). Specifically, § 1133 of ERISA provides that plans shall "provide adequate notice

in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant." 29 U.S.C. § 1133. Under the regulations promulgated pursuant to ERISA, the notification of "any adverse benefit determination" must "set forth, in a manner calculated to be understood by the claimant":

> (i) The specific reason or reasons for the denial; (ii) Reference to the specific plan provisions on which the determination is based; (iii) A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary; and (iv) A description of the plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under section 502(a) of the Act following an adverse benefit determination on review.

29 C.F.R. § 2560.503-1(g)(1).

In determining whether an insurer's notification substantially complied with these regulations, courts have looked to a number of factors, with a focus on whether the notice "permit[ted] a sufficiently clear understanding of the administrator's position to permit effective review." *See Halpin*, 962 F.2d at 690. Where a notification consisted of a non-substantially compliant letter as well as the minutes of a committee meeting during which the committee decided to deny the claim, for example, the court held that the letter and the minutes together substantially complied by identifying "each item considered" and indicating the reasoning underlying the decision. *See Brown v. Retirement Comm. of Briggs & Stratton Retirement Plan*, 797 F.2d 521, 535-36 (7th Cir. 1986). In *Halpin*, on the other hand, where the letters sent to the beneficiary did not adequately identify the items considered by the administrator or indicate the administrator's assessment of those items, the court found that the administrator's response did not meet the "substantial compliance" requirement. *See* 962 F.3d at 694. The court in *Halpin* noted that the

letters failed to explain why the administrator did not consider rehabilitative employment when at least two of its own experts mentioned that option. *See id.* at 694-97. Similarly, in *Hackett*, the Court found that the administrator failed to substantially comply because the notice provided to Hackett contained "no weighing of the evidence for and against" and "there were no articulated reasons given for Xerox's rejection of the evidence that Hackett was unable to work." 315 F.3d at 775 (explaining that "[c]onclusions without explanation do not provide the requisite reasoning and do not allow for effective review"). Xerox would have substantially complied, however, if its doctor had explained his deviation from previous opinions or provided any non-arbitrary explanation for the decision. *See id.*

Here, in spite of the fact that many of the letters sent to Jacobs fail to comply with the requirement in both the regulations and the Policy itself to provide "[r]eference to the specific plan provisions on which the determination is based," *see* 29 C.F.R. § 2560.503-1(g)(1), the explanations provided in the letters are "sufficient to permit effective review." *See Hackett*, 315 F.3d at 775. Unlike in *Hackett* and *Halpin*, the letters provide clearly articulated reasoning that demonstrates consideration of the evidence presented. *See Hackett*, 315 F.3d at 775; *Halpin*, 962 F.3d at 694. The March 29, 2006 letters denying Jacobs' IMRT claim, for example, explain that MES's peer review physician determined that IMRT was not sufficiently investigated to establish that it was more effective than standard radiation therapy and that IMRT was not considered the standard of care for Jacobs' type of cancer. The July 24, 2006 letter denying MD Anderson's appeal similarly states that IMRT was "not sufficiently investigated to show that it is more effective than standard radiation therapy and that the treatment is not considered standard of care." With respect to the Avastin and Abraxane regimen, Guardian's November 21, 2007 denial letter noted that there were

no approved clinical trials testing the use of an Avastin and Abraxane combination for Jacobs' diagnosis. The letter further informed Jacobs that an independent peer reviewer had concluded that this combination was experimental and not medically necessary and that "[e]xperimental treatment and those determined to not be medically necessary are not a covered benefit under your plan." In Guardian's September 30, 2008 and December 4, 2008 letters again denying coverage for Jacobs' Avastin and Abraxane treatment, it explained that an "independent physician consultant determined that treatment with Abraxane plus Avastin was not provided as part of an approved clinical trial, would be considered an investigational treatment for the member's diagnosis and would not be considered medically necessary for this member." Like in *Smith v. Health Services of Coshocton*, where the court found substantially compliant a letter stating that the denial was based on the determination of an independent reviewer indicating that the requested procedure was not in compliance with the policy at issue, 314 Fed. Appx. 848, 857-58 (6th Cir. 2009), these letters supplied Jacobs with sufficient reasoning by summarizing the independent reviewers' determinations pursuant to the Policy.

Similarly, in its January 22, 2009 and May 12, 2009 denial letters for single uses of Avastin and Abraxane, Guardian informed Jacobs that outside, independent physician consultants had determined that these treatments were not medically necessary for his condition. Finally, Guardian's August 31, 2009 letter explained that it had reviewed the treatment regimen of Abraxane combined with Irinotecan, and an independent peer review consultant had determined that the combination was not guideline-recommended for his cancer type and that no independent studies supported its use. These letters each provided Jacobs with "a statement of reasons that, under the circumstances of the

case, permit[] a sufficiently clear understanding of the administrator's position to permit effective review." *See Halpin*, 962 F.2d at 690.

As the court found in *Smith*, 314 Fed. App'x. at 857 n.8, the responses of Jacobs' treating physicians in their letters supporting his appeals also demonstrate their understanding of the explanations provided in the letters to Jacobs. *See id.* (explaining that "[w]hen responding to this first decision letter, Smith's doctors spoke to the conclusion that the panniculectomy was a cosmetic and not a medically necessary procedure, thereby demonstrating Smith's (and their) understanding of the reasoning behind Medical Mutual's denial of coverage"). In MD Anderson's April 25, 2006 letter of appeal on behalf of Jacobs, his treating physician opined that "[i]n uncommon disease sites, it will never be possible to demonstrate with adequate certainty in scientific studies that this methodology improves outcome." Similarly, the University Medical Center in Tuscon's appeal letter sent on December 26, 2007 contained a copy of an email stating with respect to the experimental nature of Jacobs' treatment: "there is not much, a case report and phase I study. I think the driving point should be that beyond [sic] there are no approved and known effective treatments for this disease and he is still strong to tolerate therapy and he is responding to this therapy." Each of these letters undermines Jacobs' claim that the explanations were inadequate by demonstrating an understanding of the medical necessity and experimental treatment rationales provided in the preceding denial letters.

Each of the denial letters sent to Jacobs also complies with the regulations and the Policy requirements that the letters provide a detailed scientific explanation and describe the internal rule relied upon *or* provide a copy of that information upon request by explaining that Jacobs could obtain, free of charge, "all information pertaining to this determination"--including, presumably, the

peer review physician reports and internal guidelines relied upon. *See* 20 C.F.R. § 2560.503-1(h)(2) (requiring that the claims procedures "[p]rovide that a claimant shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits"). Thus, more detailed reasoning and support for the adverse benefit determinations was available to Jacobs, and is currently available to the Court, in a way that permits its effective review of the claim denials. *See Halpin*, 962 F.2d at 690.

2. Requirement of Review that Accounts for all Information Provided by the Claimant

Jacobs next contends that Defendants failed to procedurally account for the information provided by Jacobs' treating physicians about the efficacy of the treatments for Jacobs as required under the regulations. *See* 20 C.F.R. § 2560.503-1(h)(2) (requiring that the claims procedures "[p]rovide for a review that takes into account all comments, documents, records, and other information submitted by the claimant relating to the claim"). A review of each of the denial letters, however, evidences sufficient consideration of the information provided by Jacobs' treating physician to demonstrate substantial compliance. *See, e.g.*, *Halpin*, 962 F.2d at 690 ("In determining whether a plan complies with the applicable regulations, substantial compliance is sufficient," meaning that the ultimate question is whether the court may effectively review the administrator's decision). To begin, there is no evidence in the record that Jacobs' treating physician sent a letter to MES before the initial IMRT review. MD Anderson submitted a letter in conjunction with its appeal of the denial of IMRT therapy, however, and MRI's report reviewing that appeal indicates that among the records considered was MD Anderson's appeal letter. Although MRI's report did not directly address MD Anderson's explanations about the efficacy of the treatment for Jacobs, Guardian addressed these explanations in its subsequent July 24, 2006 denial letter through its

statement that the denial was based on MRI's evaluation of whether IMRT proved efficacious for treatment of Jacobs' type of cancer and not whether it proved efficacious for treatment of Jacobs himself.

With respect to the Abraxane and Avastin treatment, although Jacobs argues Guardian should have consulted with Jacobs' treating physician about the medical necessity or experimental nature of the treatment during its first review in November 2007, there is no evidence that his treating physician submitted a letter on his behalf until June 2, 2008, after he appealed the denial of benefits. Guardian's September 30, 2008 and December 4, 2008 letters do not respond to many of the specific concerns voiced in the letter of Jacobs' treating physician; they do, however, refer to the independent consultant reviews. In MCMC's independent review on January 15, 2008, Dr. Marciniak directly addressed the information presented by Jacobs' treating physician, explaining that there were no studies of Avastin or Abraxane as monotherapy for cholangiocarcinoma and that the reference provided by Jacobs' treating physician was not of a combination of Abraxane and Avastin, but rather referred to a phase I trial of Abraxane and Carboplatin.

Importantly, unlike in *Love* where the court expressed frustration over "the fact that neither [the independent medical consultant's] report nor [the insurer's] letter addressed the contrary findings of Love's treating physicians or explained why Liberty Mutual chose to discredit them," 574 F.3d at 397, here the opinions of Jacobs' treating physicians were not "contrary" to the findings of the independent reviewers so as to require evidence that one was weighed against the other. In *Love*, the findings of Love's treating physician directly contradicted the conclusions of the independent medical consultant regarding her functional capacity supporting the continuation of disability benefits. *See id.* at 396-97. Here, the opinions of Jacobs' treating physicians pertained

to the efficacy and necessity of the treatment for Jacobs personally, whereas the independent reviewers addressed the medical necessity and experimental nature of each treatment for Jacobs' type of cancer. Whether Defendants should have considered the efficacy of the treatments for Jacobs personally goes not to whether the letters were procedurally proper, but to the substance of Defendants' denial of benefits (addressed in Section II(B)(2) *infra*).

3. Requirement of Identification of Experts Relied Upon

Finally, Jacobs argues that Defendants failed to comply with the ERISA procedural requirements and the Policy by relying on peer review physicians who they frequently failed to identify by name. The regulations promulgated pursuant to ERISA provide that a claims procedure must "[p]rovide for the identification of medical or vocational experts whose advice was obtained on behalf of the plan in connection with a claimant's adverse benefit determination, without regard to whether the advice was relied upon in making the benefit determination." *See* 29 C.F.R. 2560.503-1. The Policy itself further requires Guardian to "identif[y] medical experts whose advice was obtained in connection with an adverse benefit determination."

In a similar case also involving an ERISA policy issued by Guardian, the plaintiff argued that "Guardian's Doctors should have been identified so the court could consider the reasonableness of their conclusions," pointing to a provision in the relevant policy stating that Guardian would "identify medical or vocational experts whose advice was obtained in connection with an adverse benefit determination." *See, e.g., Gaines v. Guardian Life Ins. Co. of Am.*, No. AW-09-1762, 2010 WL 1759579, at *7 (D. Md, Apr. 30, 2010) (Williams, J.). Like the Defendants here, Guardian argued in *Gaines* that it had fulfilled its obligations by identifying each reviewer's "medical specialty, board certifications, years of practice, and/or reviewing credentials" in the reports. *See*

id. The Court found that although "Guardian should have provided some sort of further identifying information of at least one of the medical consultants, upon Plaintiff's request," the failure to provide further information did not "require[] a remand or denial of summary judgment" because "Guardian has substantially complied with ERISA's identification requirement and in any case, Gaines has not shown how lack of access to the names of the reviewing physicians has deprived her of an appropriate claim decision." *See id.* at *8; *see also Ortlieb v. United HealthCare Choice Plans*, 387 F.3d 778, 783 (8th Cir. 2004) ("Although the letter did not refer to Dr. Beer by name," the letter substantially complied with ERISA by informing Ortlieb that a physician consultant made "an independent determination that the previous decision should be upheld"). Similarly here, Jacobs "has not shown how identification by credentials, rather than identification by name, has negatively impacted [his] claim review." *See Gaines*, 2010 WL 1759579, at *8. Nor do the facts show that Jacobs ever sought and was denied the names or other identifying information about the unidentified peer review physicians. *See id.* Indeed, unlike in *Gaines*, three of the peer review physicians were identified on their reports--Dr. Kim, Dr. Kalmaldi, and Dr. Marciniak–and Jacobs presents no evidence challenging their credentials or opinions. *See id.* For these reasons, the Court finds that Defendants substantially complied with both the ERISA and Policy requirements to provide for the identification of the peer review physicians.

4. Conclusion

In conclusion, the independent peer review physicians' reports considered the relevant evidence and clearly articulated conclusions about the medical necessity and experimental nature of Jacobs' treatments. The letters provided to Jacobs summarized these reports in clear terms and stated that all information forming the basis for the determinations would be made available to

Jacobs upon request, in compliance with the regulations. Finally, all of the letters provided appeals instructions or referred Jacobs to corresponding letters outlining appeal procedures for the decisions whereby he could submit his own evidence supporting his claims.[3] Notably, as Defendants emphasize, Jacobs nowhere explains how Defendants' procedural failures hindered his ability to provide additional documentation impacting Guardian's assessment that his regimens were experimental in nature. *See Brehmer v. Inland Steel Indus. Pension Plan*, 114 F.3d 656 (7th Cir. 1997) (rejecting plaintiff's argument that denial letters were insufficient because "substantial compliance can be deemed to have occurred" where "the administrator needed no additional information to reach her determination" and the plaintiff "ha[d] not pointed out unresolved factual questions upon which further information would have been required"). For these reasons, the Court finds that Defendants' letters were sufficient to allow for effective review and hence substantially complied with the ERISA requirements set forth in § 1133 and the accompanying regulations. *See, e.g.*, *Brown*, 797 F.2d at 534 ("the persistent core requirements of review intended to be full and fair include knowing what evidence the decision-maker relied upon, having an opportunity to address the accuracy and reliability of that evidence, and having the decision-maker consider the evidence presented by both parties prior to reaching and rendering his decision") (internal citation and quotation marks omitted); *Smith*, 314 Fed. Appx. at 857-58 (finding that "Medical Mutual substantially complied with the ERISA notice requirements" by stating that Smith could obtain documents relied upon in making the appeal decision upon request and free of charge, setting forth the appeals procedure, and explaining that "after a review of the provided medical record and other

[3] The Court notes that Jacobs does not object to the notices he received under 29 C.F.R. § 2560.503-1(g)(1)(iii) &(iv) on the basis of their description of additional information necessary to perfect his claims or the description of review procedures.

materials, it had determined that the procedure was cosmetic and therefore not covered by Smith's Plan because there was no documented functional impairment").

B. Defendants' Substantive Review of Jacobs' Claims

Defendants assert that their claim denials were not arbitrary and capricious as a matter of law pursuant to § 1132(a)(1)(B) of ERISA because, in each case, the benefits for which Jacobs sought coverage were excluded under the unambiguous terms of the Policy. Specifically, Defendants claim that each of Jacobs' treatments fell within the Policy's exclusions for experimental and non-medically necessary treatment. Jacobs disputes this interpretation, asserting that the Policy explicitly covered each of his treatments. The Court first considers the parties' varying interpretations of the Policy and then assesses Defendants' application of the Policy terms to Jacobs' treatment regimens under the arbitrary and capricious standard of review. Finally, the Court addresses Jacobs' arguments that Defendants arbitrarily and capriciously failed to properly credit the opinions of Jacobs' treating physicians, improperly relied on the reports by the peer review physicians, and operated under a conflict of interest.

1. Interpretation of the Policy

"A claim for benefits under an ERISA-governed plan is a matter of contract interpretation. When there are no triable issues of fact, . . . contract interpretation is a subject particularly suited to disposition by summary judgment." *Bechtold v. Physicians Health Plan of N. Ind., Inc.*, 19 F.3d 322, 325 (7th Cir. 1994) (internal citation and quotation marks omitted). Here, there are no disputed issues of material fact, and because the terms of the Policy are unambiguous,[4] its "interpretation .

[4] Neither party argues that the relevant Policy language is ambiguous. A contract is ambiguous "only if both parties were reasonable in adopting their different interpretations of the contract." *Murphy v. Keystone Steel & Wire Co.*, 61 F.3d 560, 565 (7th Cir. 1995). The burden rests on the party trying to establish ambiguity to produce objective facts showing that a provision is ambiguous. *Id.* Ambiguity is significant in the insurance policy context because "the burden shifts to the insurer to show that the ambiguity should be resolved in its favor" if "there is ambiguity in an insurance policy." *See Anetsberger v. Metro. Life Ins. Co.*, 14 F.3d 1226, 1231 (7th Cir. 1994) ("[A] court is to construe any ambiguous

. . is a question of law for the court." *See id.* Under the arbitrary and capricious standard of review, the Court must determine whether Defendants' adverse benefit determinations were "based upon a reasonable interpretation of the plan documents." *See Carr v. The Gates Health Care Plan*, 195 F.3d 292, 294 (7th Cir. 1999).

Under the Policy, medical services are (i) covered; (ii) covered with special limitations; or (iii) excluded. The section of the Policy entitled "Other Covered Medical Services and Supplies" states: "[w]e cover anesthetics and their administration; inhalation therapy; hemodialysis; radiation and chemotherapy." Defendants interpret this provision to be subject to the Policy's general exclusion of experimental and non-medically necessary treatment. Jacobs argues that Defendants' interpretation is unreasonable because "exclusions" cannot apply to prevent coverage for a procedure that falls within one of the categories listed as "covered."

In construing the terms of "[a]n ERISA plan," "federal principles of contract construction apply." *Bland v. Fiatallis N. Am., Inc.*, 401 F.3d 779, 783 (7th Cir. 2005). "Under these rules, a document should be read as a whole with all its parts given effect, and related documents must be read together." *Id.* Jacobs essentially asks the Court to read the Policy provision regarding radiation and chemotherapy in isolation, without regard to other Policy language directly supporting Defendants' interpretation. For instance, the first three sentences of the "Covered Charges" section of the Policy explain: "[t]his section lists the types of charges we cover. But what we pay is subject to all the terms of this plan. Read the entire plan to find out what we limit or exclude." The definition of "Covered Charges" in the Glossary similarly states: "Subject to all of the terms of this *plan*, we pay benefits for *covered charges*. . . . Read the entire *plan* to find out what we limit or

language strictly against the insurer and in favor of coverage" when interpreting an insurance policy). Because neither party argues, let alone produces objective facts to show, that the relevant Policy provisions are ambiguous, this burden shifting framework does not apply here. *See Murphy*, 61 F.3d at 565.

exclude." Under a reasonable interpretation of these provisions, the examples of "anesthetics and their administration; inhalation therapy; hemodialysis; radiation and chemotherapy" are "types of charges" generally covered, but subject to all of the limitations and exclusions set forth in the remainder of the Policy–including the exclusions of experimental and non-medically necessary treatment.

The Policy's Glossary further defines "Covered Charges" as services and supplies that are "(b) medically necessary to diagnose or treat a *sickness* or *injury*; (c) accepted by a professional medical society in the United States as beneficial for the control or cure of the *sickness* or *injury* being treated; and (d) furnished within the framework of generally accepted management currently used in the United States." (Compl., Exhibit A, p. 102.) Based on this language, Defendants were reasonable to interpret the listed types of covered charges to be subject to an overall medical necessity limitation based on the particular "sickness or injury" being treated. Indeed, this precise language, with its focus on the sickness or injury at issue, is then echoed in the medical necessity "exclusion" (stating that the Plan will not pay for services that are not "medically necessary to diagnose or treat a *sickness* or *injury*") and in the definition of "experimental treatment" (as treatment not "accepted by a professional medical society in the United States as beneficial for the control or cure of *sickness* or *injury* being treated"). If the experimental nature or medical necessity of a treatment for a particular sickness or injury became inapposite once that broad treatment category was listed in the "covered" section, then these provisions would lose much of their meaning and the language warning the beneficiary that "this section lists the types of charges we cover . . . read the entire plan to find out what we limit or exclude" would be rendered meaningless. *See Bland*, 401 F.3d at 783 ("a document should be read as a whole with all its parts

given effect"). For these reasons, the Court finds that Defendants' adverse benefit determinations were "based upon a reasonable interpretation of the plan documents." *See Carr*, 195 F.3d at 294.[5]

2. Application of the Policy Terms to Jacobs' Treatment Programs

Because Defendants' interpretation of the Policy was reasonable, the next step is to determine whether Defendants "downright unreasonable" in their application of the Policy terms to Jacobs' claims. *See Carr*, 195 F.3d at 294 (it is not the court's function "to decide whether [it] would reach the same conclusion as [an administrator] or even rely on the same authority. Instead, the court is only to determine if the decision was downright unreasonable.").

The Policy states that Guardian does not:

> pay for services and supplies which are not: (a) furnished or ordered by a recognized provider; (b) medically necessary to diagnose or treat a *sickness* or *injury*; (c) accepted by a professional medical society in the United States as beneficial for the control or cure of the *sickness* or *injury* being treated; and (d) furnished within the framework of generally accepted methods of medical management currently used in the United States.
>
> We don't pay for *experimental treatment.*

"Experimental treatment" is defined under the Policy as treatment:

> (a) that has not been scientifically proven or fully developed; (b) cannot be supported in medical literature published by a professional medical society in the United States; (c) is not accepted by a professional medical society in the United States as beneficial for the control or cure of *sickness* or *injury* being treated; or (d) is not furnished within the framework of generally accepted methods of medical management currently being used in the United States.

[5] In his reply brief, Jacobs points to a provision in the Policy under "Charges Covered With Special Limitations/Investigational Cancer Treatments" stating: "[u]nless this plan provides specific benefits, we don't cover any other charges for routine care or experimental treatment." (R. 58, p. 3 (citing Compl. Exhibit A, p. 77)). Jacobs argues that from this provision the opposite principle is implied–that when the Policy provides for a specific benefit it will cover even experimental charges. The Court does not find other support for this proposition in the Policy so as to render Defendants' interpretation unreasonable. Instead, the provision stating "this [Covered Charges] section lists the types of charges we cover" but "[r]ead the entire plan to find out what we limit or exclude" directly implies the opposite–that types of covered charges listed in the Policy are subject to the exclusions.

Because the experimental treatment provision is set forth in the "exclusions" section of the policy, Defendants have the burden of establishing that it applies to Jacobs' treatments. *See Fuja v. Benefit Trust Life Ins. Co.*, 18 F.3d 1405, 1408 (7th Cir. 1994); *see also Mario v. P & C Food Markets, Inc.*, 313 F.3d 758, 765 (2d Cir. 2002) ("Where instead lack of medical necessity is set forth in the 'exclusions' section of the plan, the burden is usually on the plan sponsor, who must prove that the exclusion applies."). "If the administrator makes an informed judgment and articulates an explanation for it that is satisfactory in light of the relevant facts, then the administrator's decision is final." *See Carr*, 195 F.3d at 294.

Here, Defendants' denials were based on informed judgments pursuant to the Policy that were articulated in each letter sent to Jacobs denying coverage. *See Carr*, 195 F.3d at 294. Defendants sought independent peer review physician opinions regarding the medical necessity and experimental nature of each treatment, and in a total of eight peer review reports by three different peer review agencies, independent peer review physicians opined that his treatments were not medically necessary, experimental, not supported by sufficient clinical studies, or not accepted by a professional medical society in the United States as appropriate for treatment of Jacobs' type of cancer. More specifically, Defendants' initial decision regarding IMRT therapy was supported by Dr. Kim's finding in MES's report that no published reports of prospective randomized clinical studies involving IMRT existed at the time. Similarly, the IMRT appeal was supported by the uncontradicted finding in the MRI peer review that "[i]n the most current edition of the NCCN Clinical Guidelines for Heptobiliary Cancers, radiation therapy is not indicated as an acceptable option for management of metastatic intrahepatic cholangiocarcinoma except as might be needed for comfort care." The peer review physician further explained that "[t]he literature on IMRT for

this particular diagnosis is sparse and represents a limited number of patients in studies of poor quality concentrating mainly on technical feasibility and safety; IMRT cannot be considered 'sufficiently investigated' to establish its usefulness." Guardian's subsequent July 24, 2006 letter denying Jacobs' appeal for IMRT therapy stated that it was relying on MRI's evaluation of whether IMRT proved efficacious for treatment of Jacobs' type of cancer–that is, metastatic intrahepatic cholangiocarcinoma--and not whether it proved efficacious for treatment of Jacobs himself.

Similarly, with respect to the Abraxane and Avastin combination regimen, the peer review physician noted that the National Cancer Institute's Physician Data Query website showed no clinical trials for the combination of Avastin and Abraxane. A second peer review physician from a separate agency, Dr. Kalmadi, also reviewed the Abraxane and Avastin combination and concluded that:

> The use of Abraxane/Avastin is not being provided as part of an approved clinical trial. This is being provided as off label use of these drugs . . . . Given the member's diagnosis the use of Abraxane and Avastin is an investigational cancer treatment. It does not have approval by the Food and Drug Administration (FDA), compendium listed, randomized control trials, or expert consensus . . . . The use of Abraxane and Avastin is not medically necessary for this member, as this has not been shown to be beneficial in randomized control trials.

In the subsequent appeal review by Dr. Marciniak, he concluded that because "there are no peer-reviewed published clinical studies of the combination of Abraxane/Avastin as a treatment for advanced cholangiocarcinoma," "it would be considered investigational and of unproved benefit. As it is of unproven benefit, it would not be considered medically necessary for this patient." With respect to the single use Avastin, single use Abraxane, and Abraxane and Irinotecan regimen, the reviewers similarly found that few if any clinical studies had demonstrated the efficacy of those regimen. MRI's review of Abraxane and Irinotecan stated in particular that: "There is no

combination [of chemotherapy] that has been proven to be more effective than another. There is no credible medical literature that second line chemo is beneficial in gallbladder cancer . . . . The continuation of [Abraxane] through consecutive lines of therapy after progression is highly experimental." The letters denying Jacobs' claims for single use Avastin, single use Abraxane, and Abraxane and Irinotecan treatments also focus on the peer review reports' conclusions that the treatments were not medically necessary for his condition, which accords with the Policy's focus on "the *sickness* or *injury* being treated." Through the evidence presented in the peer review reports and letters to Jacobs, the Court finds that Defendants met their burden of establishing that Jacobs' treatments fall under the terms of the Policy's exclusions for experimental and non-medically necessary treatment. *See Fuja*, 18 F.3d at 1408.

Moreover, Jacobs does not offer any evidence to dispute that each of his treatments is experimental under Policy's definition. He has not submitted any documentation or direct evidence to counter the opinions of the peer review physicians and show that the various treatment regimens that he underwent were scientifically proven, supported in the medical literature, accepted by a professional medical society as beneficial for the control of his illness, or within the framework of generally accepted methods of medical management currently being used in the United States. He could have attempted to demonstrate that one or more of his treatment programs had undergone sufficient clinical studies or provided medical literature showing those regimens to be beneficial for his form of bile duct cancer. There is no evidence in the record that he attempted to do so, other than his treating physician's citation of a Phase I study that did not address his combination of drugs. In *Ortlieb*, the court similarly emphasized that although the denial notices "consistently identified the bases for coverage denial--unproven service and insufficient peer-reviewed medical literature--

neither Ortlieb nor her treating physician provided United HealthCare with clinical evidence or peer-reviewed literature establishing TPN therapy was a proven therapy for Ortlieb's medical conditions." 387 F.3d at 784. Because Defendants made "an informed judgment and articulate[d] an explanation for it that [was] satisfactory in light of the relevant facts," including the lack of contradictory evidence presented by Jacobs, "this court will not substitute the conclusion it would have reached for the decision of the administrator." *Herman v. Cent. States, Se. & Sw. Areas Pension Fund*, 423 F.3d 684, 692-93 (7th Cir. 2005); *see also Exbom v. Central States, Se. & Sw. Areas Health & Welfare Fund*, 900 F.2d 1138, 1143 (7th Cir. 1990) ("If the trustee makes an informed judgment and articulates an explanation for it that is satisfactory in light of the relevant facts, i.e., one that makes a 'rational connection' between the issue to be decided, the evidence in the case, the text under consideration, and the conclusion reached, then the trustee's decision is final.").

3. Consideration of the Opinions of Jacobs' Treating Physicians

Jacobs also argues that Defendants were arbitrary and capricious in not considering the evidence provided by his treating physician about the efficacy of the treatments for Jacobs personally. Although an administrator must consider evidence submitted by a treating physician, *see Love*, 574 F.3d at 397-98, "plan administrators are not obliged to accord special deference to the opinions of treating physicians," *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 825 (2003). *See also Love v. Dell, Inc.*, 551 F.3d 333, 337 (5th Cir. 2008) ("ERISA does not require the opinions of treating physicians to be preferred over those of other physicians reviewing a file; ERISA merely requires that the opinions of treating physicians, as with all evidence submitted by the claimant, actually be taken in account in an administrator's determination."). As explained in section II(A)(2)

supra, the letters and reports relied upon by Defendants evidence consideration of the opinions of Jacobs' treating physicians.

Although the decision letters and peer review reports do not discuss these treating physician opinions in detail, this lack of discussion is justified in that the opinions of the peer review physicians and Jacobs' treating physicians did not diverge when applied to the actual Policy language. "Under the present state of the law, we are bound to interpret the language of the specific contract before us and cannot amend or expand the coverage contained therein." *Fuja*, 18 F.3d at 1412. As explained above, the language of the exclusions for experimental treatment and lack of medical necessity, as well as the definition of "covered charges" under the Policy, concentrates on treatment that has been shown effective for "the sickness or injury being treated" through medical literature or generally accepted methods of medical management. In their letters, Jacobs' treating physicians concentrated on the efficacy of the treatment for Jacobs personally. For instance, Jacobs' treating physician's June 2, 2008 letter to Guardian requesting that it reconsider its decision to deny coverage explained that under the Avastin and Abraxane treatment, Jacobs had experienced an objective and sustained tumor response with tumor marker reduction and PET-CT improvement. Similarly, in Jacobs' IMRT appeal MD Andersen opined that IMRT was selected as the safest and most effective treatment for Jacobs because of the contours of his tumor and the way it was situated in relation to his adjacent organs. These conclusions did not need to be addressed and weighed in the reports or letters because they provided no insight into whether the regimens were scientifically or fully developed, supported in medical literature, accepted by a professional medical society as beneficial for the control or cure of Jacobs' condition, and furnished within the framework of

generally accepted methods of medical management being used in the United States under the terms of the Policy.

Moreover, several of the documents and letters from Jacobs' treating physicians effectively conceded that his treatments did not qualify under the experimental treatment and lack of medical necessity exclusions. In Jacobs' first appeal letter, for example, MD Andersen noted that "[i]n uncommon disease sites, it will never be possible to demonstrate with adequate certainty in scientific studies that this methodology improves outcome." "[M]any insurance companies," it explained, "require evidence from well-controlled clinical trials published in peer-reviewed medical literature to support the non-investigational status of a medical service. [However,] this type of interpretation does not recognize the fact that the literature often lags at least one year behind the actual clinical practice and that for many medical services, these types of controlled studies may never be available." The University Medical Center in Tuscon's appeal letter on December 26, 2007 similarly included a copy of an email conceding that "there is not much, a case report and phase I study. I think the driving point should be that beyond [sic] there are no approved and known effective treatments for this disease." In MCMC's report, Dr. Marciniak specifically discounted this reference because it was not a trial of Abraxane and Avastin, but was a phase I trial of Abraxane and Carboplatin. Given these concessions and the lack of contradictory evidence presented by Jacobs' treating physicians, Guardian reasonably interpreted the Policy to exclude the use of IMRT and the chemotherapy combinations used to treat Jacobs' form of bile duct cancer because those treatments had not been proven effective for treating his condition. *See Carr*, 195 F.3d at 296-97 (the "language of the Plan controls as does the Committee's ruling as long as it is reasonable").

Jacobs argues that "there is *at a minimum*, a question of fact as to whether the uncontested efficacy of Plaintiff's treatment, as reported to Guardian by Plaintiff's treating physician, established that his treatments were neither experimental nor investigational." (R. 52, p. 8.) Although it may be the case that the efficacy of a treatment for a particular patient should be a consideration under experimental exclusions in insurance policies, "Congress never intended ERISA to dictate the *content* of welfare benefit plans, much less for the federal courts to determine the *content* of such plans." *Hickey v. A.E. Staley Mfg.*, 995 F.2d 1385,1392 (7th Cir. 1993). Moreover, "the fact that a procedure is medically necessary" for a particular patient "does not obviate the possibility that it may also be experimental" under the terms of an ERISA policy. *See Loyola Univ. of Chi. v. Humana Ins. Co.*, 996 F.2d 895, 900 (7th Cir. 1993).[6] Even though this particular Policy's focus on "medical literature published by a professional medical society" and acceptance "by a professional medical society in the United States as beneficial for the control or cure of *sickness* or *injury* being treated" seems particularly unfortunate in cases like Jacobs' with an uncommon disease site and type of cancer, "[t]his is a contract case and the language of the benefit plan controls." *See id.* at 901, 903 (explaining that although "it seems callous for Humana to deny coverage for a lifesaving procedure and thereafter deny all subsequent hospital expenses," "Humana's humanity is not the issue here," and "[t]he experimental nature and research of the Jarvik heart implantation are not diminished just because the procedure was the only choice and happened to be successful" for him); *see also Esdale*

[6] Although Jacobs further contends that Guardian or its peer review physicians should have contacted his treating physicians to discuss his medical condition and the treatments being provided to him, ERISA does not require a claims administrator or peer review physician to contact a treating physician in rendering a determination. *See Davis*, 444 F.3d at 577 ("The district court and Davis also fault Unum for relying on 'a mere paper review,' lamenting the fact that Unum's doctors did not personally examine Davis or speak with his doctors. However, neither the district court nor Davis has cited, and our research has not disclosed, any authority that generally prohibits the commonplace practice of doctors arriving at professional opinions after reviewing medical files. In such file reviews, doctors are fully able to evaluate medical information, balance the objective data against the subjective opinions of the treating physicians, and render an expert opinion without direct consultation.").

v. American Cmty. Mut. Ins. Co., 914 F.Supp. 270, 273 (N.D. Ill. 1996) (analyzing a claim for benefits under ERISA and explaining that "ERISA plan and insurance policy provisions defining medical necessity and experimental or investigational treatments differ widely," such that "in resolving issues like those presented in this case, the court must apply the specific language of the contract to the facts presented"). Like in *Santucci v. Hyatt Corporation*, 955 F. Supp. 927 (N.D. Ill. 1997), where the plaintiff's treating physician opined that a particular cancer treatment "was medically necessary in the plaintiff's case" but two physician experts concluded in written reports that it was "not standard therapy" and that "until randomized studies have been completed, no one can say whether the treatment is as good or better than the alternative treatments available," here the "evidence available to the defendants was uncontradicted: the procedure was experimental and not covered by the policy." *Id.* at 929.

4. Reliance on Reports by Independent Peer Reviewer Physicians

Jacobs next objects to Defendants' reliance on the independent peer review physicians in making their adverse benefit determinations. The Policy states that Guardian will "consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment." It is true that Dash, Guardian's Rule 30(b)(6) designee, did not, in many cases, know the identity of the individual who prepared the peer review report, the age or education of that individual, the amount of time spent reviewing records or preparing the report, the individual's employment status, whether he or she ever saw a patient, or whether he or she had been disciplined or sued for malpractice.

However, Dash testified that with respect to all of the peer review physicians, she knew the information about them that was provided in their reports. Those reports set forth detailed

descriptions of the physicians' qualifications and credentials. For example, the initial IMRT review by Dr. Kim identifies him as board certified in Radiology with a subspecialty in Radiation Oncology. The IMRT appeal review states that it was performed by a physician who had been in practice since 1978, was certified by the American Board of Radiology with a subspecialty in Therapeutic Radiology, and served as Medical Director of Radiation and Associate Professor of Radiology at a medical school in the United States. The peer review physician who performed MRI's review of the Avastin and Abraxane treatment was, according to the report, board certified in internal medicine by the American Board of Internal Medicine, Hematology, and Medical Oncology and was a member of the American Society of Clinical Oncology and the American Society of Hematology. Dr. Kalmadi from MCMC, who performed a second review of the Avastin and Abraxane treatment regimen, was a board certified specialist in Internal Medicine—Medical Oncology. Dr. Marciniak from MCMC, who performed the appeal review of the Avastin and Abraxane regimen, was M.D. board certified in internal medicine and medical oncology. The MRI peer review physician who reviewed the single use of Avastin was Acting Chief of Hematology/Oncology at a university hospital, board certified in oncology and hematology, and a member of the American Society of Clinical Oncology. The MRI peer review physician who reviewed the single agent Abraxane was board certified in internal medicine with a subspecialty in medical oncology, was a member of the American Society of Clinical Oncology, and taught gastrointestinal oncology at a cancer center. Finally, the MRI physician who reviewed Abraxane and Irinotecan treatment was board certified in internal medicine with subspecialties in oncology and hematology, Acting Chief of Hematology/Oncology at a university hospital, and also a member of the American Society of Clinical Oncology.

Jacobs sets forth no evidence suggesting that the credentials of the peer review physicians identified in the reports are false or exaggerated, or causing the Court to question the legitimacy or independence of MRI, MCMC, and MES. Jacobs also fails to cite any statutory or case law showing that lacking specific information about the peer review physician would render a determination arbitrary and capricious. Given the independent nature of the agencies consulted and insurers' frequent reliance on similar agencies in making adverse benefit determinations, Defendants' reliance upon these agencies, even without knowing how much they are compensated or their process for employing reviewers, does not rise to the level of arbitrary and capricious. *See, e.g.*, *Ortlieb*, 387 F.3d at 783-84 (explaining that an insurer's denial of coverage was reasonable where four physicians, including two "external, independent physician consultants," reviewed a beneficiary's medical file and "consistently determined TPN therapy was an unproven therapy for Ortlieb's medical conditions"); *Santucci*, 955 F. Supp. at 929-30 (concluding that it was not arbitrary and capricious for the claims administrator to rely on the opinions of two consulting oncology physicians in determining that the plaintiff's treatment fell under the experimental exclusion under the Policy); *Benisek v. Rush Prudential HMO, Inc.*, No. 98-1517, 1999 WL 498632 (N.D. Ill. July 7, 1999) (Holderman, J.) (finding that it was not unreasonable for a claims administrator to rely on the opinions of two independent physician consultants that the treatment program was investigational and experimental).[7]

[7] Despite Jacobs' argument to the contrary, Defendants also complied with the terms of the Policy for reviewing appeals through the independent review agencies. The Policy states that Guardian will "ensure[] that a health care professional engaged for consultation regarding an appeal based upon a medical judgment was neither the person who was consulted in connection with the adverse benefit determination, nor that person's subordinate." MRI conducted the review of Jacobs' first appeal of the IMRT benefits denial, and a different review agency, MES, conducted the initial review. In Jacobs' Avastin and Abraxane appeal, both a peer review physician with MRI and Dr. Kalmadi with MCMC performed initial reviews, and Dr. Marciniak from MCMC performed the appeal review.

5. Conflict of Interest

Jacobs raises one final ground upon which he argues that Defendants' decisions were arbitrary and capricious–that a conflict of interest is created when a fiduciary operates a plan as an insurer and an administrator. As explained above, because Guardian insured the Policy, processed claims under the Policy, and made determinations of benefits eligibility under the Policy, "the court is required to take such an obvious conflict of interest into consideration." *See Leger*, 557 F.3d at 831. However, unlike in *Glenn*, here there is no evidence that Guardian "had emphasized a certain medical report that favored denial of benefits, had deemphasized certain other reports that suggested a contrary conclusion, and had failed to provide its independent vocational and medical experts with all of the relevant evidence," so as to suggest that a conflict of interest affected the benefits decision. *See Glenn*, 128 S.Ct. at 2352. One further indicia of reliability is that here, like in *Santucci*, the independent peer review organizations–not Guardian–selected the physicians who conducted the reviews. *See Santucci*, 955 F. Supp. at 929. Given the Court's analysis regarding the reasonableness of the Defendants' determinations and the lack of evidence that a conflict of interest entered into the determinations at issue, the Court finds that this is not a case where "other factors are closely balanced" such that the presence of a conflict could "act as a tiebreaker." *See Fischer*, 576 F.3d at 377.

6. Conclusion

Although "cases of this nature pose most difficult policy questions of who should bear the burden of paying for expensive medical treatments that are at the time of the treatment of unknown efficacy, . . . as judges we are called upon to resolve the legal question presented . . . i.e., interpreting the . . . insurance contract." *Fuja*, 18 F.3d at 1407. "It is not our function to decide whether we

would reach the same conclusion as the Plan or even rely on the same authority." *Carr*, 195 F.3d at 294; *see also Bechtold*, 19 F.3d at 325 ("This is a matter of contract interpretation that does not implicate the broader policy issues involved in whether insurers *should* cover medical procedures that are presently of unknown medical value and extremely costly."); *Harris v. Mutual of Omaha*, 1992 WL 421489 (S.D. Ind. Aug. 25, 1992) (Tinder, J.), *aff'd*, 992 F.2d 706 (7th Cir. 1993) ("Perhaps the question most importantly raised about this case, and similar cases, is who should pay for the hopeful treatments that are being developed in this rapidly developing area of medical science."). Because the parties have presented no disputed issues of material fact and Defendants' decisions to deny benefits were not arbitrary and capricious, they are entitled to summary judgment. *See Bechtold*, 19 F.3d at 325 ("A claim for benefits under an ERISA-governed plan is a matter of contract interpretation. When there are no triable issues of fact, . . . contract interpretation is a subject particularly suited to disposition by summary judgment.").

CONCLUSION

For the foregoing reasons, the Court denies Jacobs' Motion for Summary Judgment and grants Defendants' Cross-Motion for Summary Judgment.

Virginia M. Kendall
United States District Court Judge
Northern District of Illinois

Date: July 27, 2010